NEO-PREDEF WITH TETRACAINE- neomycin sulfate, isoflupredone acetate, and tetracaine hydrochloride powder
Zoetis Inc.

Neo-Predef® with Tetracaine Powder

(neomycin sulfate, isoflupredone acetate, and tetracaine hydrochloride topical powder)

For Use in Animals Only

For topical ear and skin use in dogs, cats and horses

Caution

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

NEO-PREDEF with Tetracaine Powder contains in each gram neomycin sulfate, 5 mg (equivalent to 3.5 mg neomycin); isoflupredone acetate, 1 mg; tetracaine hydrochloride, 5 mg; myristyl-gamma-picolinium chloride (as a preservative); and lactose hydrous. Because of the prompt, potent, and specific actions of the individual components, this combination is well suited for the treatment of certain ear and skin conditions occurring in dogs, cats and horses.

ADVANTAGES OF NEO-PREDEF WITH TETRACAINE

1. Highly potent anti-inflammatory effect of isoflupredone acetate.
2. Wide-spectrum bactericidal effect of neomycin.
3. Rapid anesthetic effect of tetracaine.
4. Prompt relief of symptoms.
5. Reduces further self-inflicted trauma.
6. Ease of application.
7. Adherent to moist surfaces.

ISOFLUPREDONE ACETATE

Isoflupredone acetate markedly inhibits inflammatory reaction through its controlling influence on connective tissue and vascular components. Topically applied isoflupredone acetate is usually rapidly effective. In otitis externa, wounds of the concha, ulcerations of the ear flaps, and irritated lesions of the skin, the inflammatory response may also be effectively inhibited by isoflupredone acetate. Chronic conditions respond more slowly and relapses are more frequent.

NEOMYCIN

Neomycin is an antibiotic substance derived from cultures of the soil organism *Streptomyces fradiae*. Its antimicrobial range includes both gram-positive and gram-negative organisms commonly responsible for or associated with otic infections, such as staphylococci, streptococci, *Escherichia coli.*, *Aerobacter aerogenes*, and many strains of Proteus and Pseudomonas organisms. It is not active against fungi.

Neomycin is unusually nontoxic for epithelial cells in tissue culture and is nonirritating in therapeutic concentrations. The presence of neomycin in NEO-PREDEF with Tetracaine Powder affords control of neomycin-sensitive organisms.

TETRACAINE

Tetracaine hydrochloride is a topical anesthetic agent that is more potent than either procaine or cocaine in comparable concentration. The duration of anesthetic action of tetracaine exceeds that produced by either butacaine or phenacaine.

Many investigators have demonstrated that local anesthesia plays a significant part in the promotion of healing, especially where pain is a prominent factor. It is believed that trauma stimulates local pain receptors, which results in reflex vasodilation, edema, tenderness, and muscular spasm.

If the reflex is abolished through use of a local anesthetic such as tetracaine, amelioration of these tissue changes that interfere with healing is favored. The local anesthetic action of tetracaine has proved to be of great value in alleviating the pain reflex in painful skin and ear conditions.

INDICATIONS

NEO-PREDEF with Tetracaine Powder is indicated in the treatment or adjunctive therapy of certain ear and skin conditions in dogs, cats and horses caused by or associated with neomycin-susceptible organisms and/or allergy. In addition, it is indicated as superficial dressing applied to minor cuts, wounds, lacerations, abrasions, and for post-surgical application where reduction of pain and inflammatory response is deemed desirable. NEO-PREDEF with Tetracaine Powder may be used as a dusting powder following amputation of tails, claws, and dew-claws; following ear trimming and castrating; and following such surgical procedure as ovariohysterectomies.

Applied superficially, it has been used successfully in the treatment of acute otitis externa in dogs, acute moist dermatitis and interdigital dermatitis in the dog, and as a dusting powder to various minor cuts, lacerations, and abrasions in the horse, cat and dog.

WARNINGS

Not for human use. Do not use in horses intended for human consumption.

Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca.

PRECAUTIONS

Before instilling any medication into the ear, examine the external ear canal thoroughly to be certain the tympanic membrane is not ruptured in order to avoid the possibility of transmitting infection to the middle ear as well as damaging the cochlea or vestibular apparatus from prolonged contact. If hearing or vestibular dysfunction is noted during the course of treatment discontinue use of NEO-PREDEF with Tetracaine Powder.

Incomplete response or exacerbation of corticosteroid-response lesions may be due to the presence of nonsusceptible organisms or to prolonged use of antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly Monilia. Thus, if improvement is not noted within two or three days, or if redness, irritation, or swelling persists or increases, the diagnosis should be

redetermined and appropriate therapeutic measures initiated.

APPLICATION

After cleansing the affected area, NEO-PREDEF with Tetracaine Powder is applied by compressing the sides of the container with short, sharp squeezes. In most instances a single daily application will be sufficient; however, it may be applied one to three times daily, as required.

HOW SUPPLIED

NEO-PREDEF with Tetracaine Powder is available in 15 gram plastic insufflator bottles. Because of the hygroscopic properties of neomycin sulfate, **this bottle should be stored in a dry place.** The cap should be replaced when the bottle is not in use. This puffer bottle has been designed to permit dusting when held in any position. Protecting the outlet from moisture will aid in assuring proper function; therefore, **the tip should not be allowed to come in contact with moist membranes or weeping surfaces.**

STORAGE

Store in a dry place at controlled room temperature 20° to 25°C (68° to 77°F).

Approved by FDA under NADA # 015-433

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

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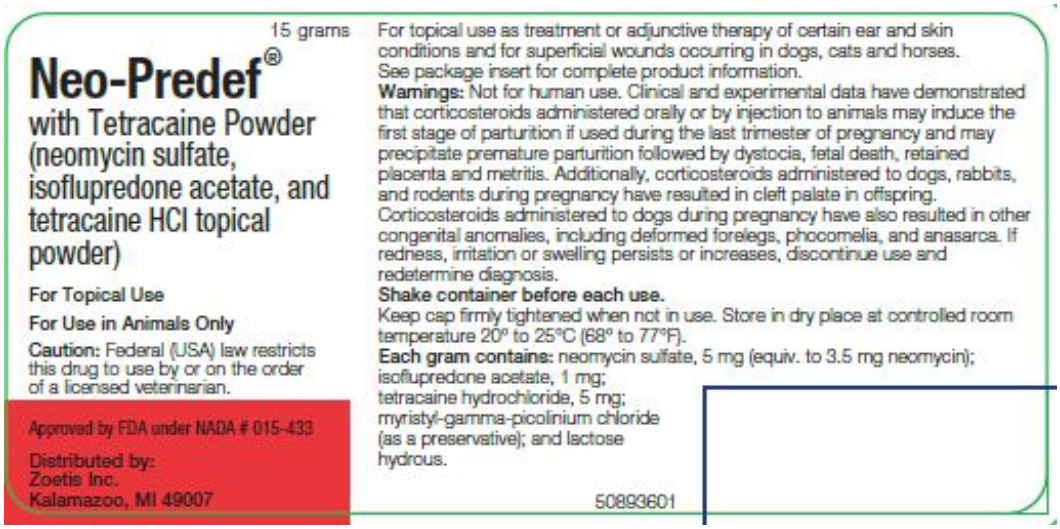
PRINCIPAL DISPLAY PANEL - 15 g Bottle Label



NEO-PREDEF WITH TETRACAINE
neomycin sulfate, isoflupredone acetate, and tetracaine hydrochloride powder

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:54771-1584
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	5 mg in 1 g
ISOFLUPREDONE ACETATE (UNII: 55P9TUL75S) (ISOFLUPREDONE - UNII:HYS0B45Z2S)	ISOFLUPREDONE ACETATE	1 mg in 1 g
TETRACAINE HYDROCHLORIDE (UNII: 5NF5D4OPCI) (TETRACAINE - UNII:0619F35CGV)	TETRACAINE HYDROCHLORIDE	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-1584-1	15 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA015433	01/13/1965	

Labeler - Zoetis Inc. (828851555)

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